Methodist College
UnityPoint Health

METHODIST COLLEGE

INSTITUTIONAL REVIEW BOARD

TYPES OF REVIEWS

Research projects are reviewed at one of three levels, according to the IRB's determination of the projects potential risk to human subjects and federal guidelines that define the categories of review, which are:

- Screening for exemption from full review,
- Expedited IRB review, and
- Full convened IRB review

The level of review is determined only by the IRB.

Screening for exempt status

Investigators do not have the authority to determine whether research involving human subjects is exempt from full review 45 CFR 46.101(b) and (c) & 21 CFR 56.104(c) and (d).Hence, while research that involves only minimal risk to human subjects is sometimes exempt from full IRB committee review, it is still subject to IRB review. Researchers must file an application requesting that the IRB determine exempt status for a project.
In general, the federal guidelines for research on human subjects allow a project to be exempt from full review only if the research involves *no risk* to the subject and the procedures are limited to the following criteria:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,
(i) if wholesome foods without additives are consumed or
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Projects that involve contact with subjects may still qualify as exempt. Copies of the written consent form should be filed with the application or justification for a waiver of written documentation should be provided. See 45 CFR 46.117.
The application form is available on the Methodist College Web site.
The IRB administrator decides whether the project qualifies as exempt, and the decision is confirmed in writing, most often within one week. If the project does not qualify as exempt, it is referred back to the investigator with the appropriate application forms.

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Expedited review

To qualify for expedited review, a research procedure must be limited to the activities that are federally approved (from 63 FR 60364-60367, November 9, 1998.) for expedited review and incur no more than *minimal risk* for participants, or be a *minor* change in previously approved research that involves *no additional risk* to the research subject.
The activities approved in the federal regulations for expedited review are:

1. Clinical studies of drugs and medical devices
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior
8. Continuing review of research previously approved by the convened IRB
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

The researcher must demonstrate in the application how the proposed project activities fall into one or more of these categories.
To apply for expedited review, investigators complete Application Form and indicate that they are requesting expedited review in the appropriate section.
The IRB administrative staff assures that all the elements essential for review, including consent forms and supporting information, have been submitted. The application is then forwarded to a designated

committee member for review and decision. Either the research is approved (perhaps with stipulations) by the committee member or it is forwarded for full review.

Full review

A project that involves greater than minimal risk requires approval by an IRB panel composed of members qualified to review research in that field. Research that requires full committee review includes:

- research that involves greater than minimal risk
- non-exempt research that involves children or other vulnerable populations;
- research that involves experimental drugs or devices;
- research that involves invasive procedures; and
- research that involves deception.

Survey research that involves sensitive questions or information about sexual practice or illegal behavior is subject to full review, in keeping with federal guidelines. Any survey or interview that is likely to be stressful for the subject requires full committee review. IRB staff will make this determination.
All applications are screened by the IRB; if the application is incomplete, it is returned to the investigator. After review by the IRB panel, the application will be:

- approved as submitted;
- approved with minor suggestions for changes;
- approved with stipulations (conditions that must be met before final approval is granted) - *most common*;
- deferred, pending receipt of additional information or major revisions; or
- not approved.

All non-exempt research is subject to continuing review at least annually. If research involves significant risk to subjects, the IRB may require more frequent review and may ask to be kept apprised of all research activity. For example, researchers in acute care settings or whose research involves novel therapies are asked to submit their protocols for frequent review.

Class Protocols for Research Methods Courses

If the overall objective of a course assignment is to learn about the design and conduct of research projects, and if data will be collected and analyzed for classroom learning only, a request for approval of a Class Protocol should be filed with the IRB by submitting an application.
If the same Class Protocol will be used in several courses during an academic year, the IRB may be able to approve all uses with a single application. The protocol must be *reevaluated annually*, however, to ensure that the guidelines are maintained and to bring the protocol up to date with any changes in the federal guidelines.
Very ambitious projects and projects that involve sensitive topics and vulnerable populations are not suited to the Class Protocol process. These must be pursued as individual projects.
An example of an acceptable Class Protocol is a course in psychology taught several times per year by different faculty members. The course involves a cluster of independent projects conducted by the students. In this case, students complete IRB application forms and submit them to their instructors for review and approval. The Course Protocol adheres to the following terms:

- the instructor will direct students to complete basic level training for human subject protection
- student projects will be reviewed by course faculty;
- students will draw their research subjects from the student population (if extra credit points are awarded to subjects, a faculty member will determine whether the points awarded are appropriate in light of the time spent by the subject);
- student projects will not involve any personal, sensitive, or incriminating topics or questions that could place subjects at risk;
- the projects will not manipulate the behavior of students in any way beyond the range of normal classroom activity or college life; and
- the projects will not involve physically or psychologically invasive contact with the subjects.

Application forms and original signatures

All forms that an investigator must file with the IRB to apply for review are available, with specific instructions. The forms are available on the College website under IRB.

- Forms must not be handwritten.
- Fill out all of the questions on form completely (If there are questions about using the text form fields or checkboxes with this form.
- Make sure to include the e-mail address and employee/student ID numbers of the PI, Co-investigators and all other personnel.
- Fill out and attach the appropriate appendices required by responses in this application.
- Attach supporting documentation: consent form(s), assent form(s), protocol, survey instruments, interview schedules, solicitation letters, advertisements, letters of permission, etc.
- Complete the checklist that accompanies this form to assure all requirements for submission are completed so that review is not delayed.
- Submit this application and appendices along with the supporting documentation to the Institutional Review Board at Methodist College